Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

STATE MEDICAID POLICIES AND OVERSIGHT ACTIVITIES RELATED TO 340B-PURCHASED DRUGS

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June 2011
OEI-05-09-00321

EXECUTIVE SUMMARY

OBJECTIVE

To describe State Medicaid agencies' policies and oversight activities related to drugs purchased under the 340B Drug Discount Program.

BACKGROUND

The 340B Drug Discount Program (340B Program) requires drug manufacturers to provide covered outpatient drugs to certain eligible health care entities, known as covered entities, at or below statutorily defined discount prices (340B ceiling prices). After a Federal *qui tam* lawsuit alleged that covered entities overcharged Medicaid for drugs purchased under the 340B Program (340B-purchased drugs), Senator Charles Grassley requested that the Office of Inspector General describe Medicaid reimbursement practices related to the 340B Program.

The Health Resources and Services Administration (HRSA), the agency that administers the 340B Program, has issued guidance regarding billing of 340B-purchased drugs. In 1993, HRSA directed covered entities to bill State Medicaid agencies at actual acquisition cost (AAC) for 340B-purchased drugs. In 2000, HRSA issued new guidance directing covered entities to instead refer to State Medicaid agencies' policies for applicable billing policies. The Patient Protection and Affordable Care Act (ACA) requires the Secretary to issue new guidance describing methodologies available to covered entities for billing 340B-purchased drugs to State Medicaid agencies.

State Medicaid agencies generally create State-specific billing and reimbursement policies and may also choose to do so specifically for 340B-purchased drugs that covered entities dispense to Medicaid patients (referred to as 340B policies). The Centers for Medicare & Medicaid Services (CMS), which administers the Medicaid program at the Federal level, does not require State Medicaid agencies to set 340B policies.

When reimbursing for 340B-purchased drugs, State Medicaid agencies have a responsibility to accurately reimburse covered entities and appropriately claim Medicaid rebates from drug manufacturers. State Medicaid agencies can use prepay edits and postpay reviews to ensure accurate reimbursements. With respect to rebates, State Medicaid agencies should exclude claims for 340B-purchased drugs (340B claims) from Medicaid rebate requests to prevent subjecting drug manufacturers to duplicate discounts (i.e., selling 340B-purchased drugs

to covered entities at the discounted ceiling prices and providing Medicaid rebates on the same drugs).

HRSA created the Medicaid Exclusion File to help State Medicaid agencies identify 340B claims. The ACA requires that the Secretary develop procedures for covered entities to annually update their information in HRSA's covered-entity database, from which the file is derived.

In March 2010, we surveyed 50 State Medicaid agencies and the District of Columbia's Medicaid agency (hereinafter referred to as States) about their policies and oversight activities related to 340B-purchased drugs. We received responses from all 51 States.

FINDINGS

Approximately half of States have written 340B policies that direct covered entities to bill Medicaid at cost for 340B-purchased drugs. Twenty-five States reported having written policies that direct covered entities to bill at AAC for 340B-purchased drugs, while 25 States do not have written policies. One State has a written policy to reimburse 340B-purchased drugs at rates other than AAC. Over half of States without written 340B policies reported that they rely on HRSA's 1993 guidance directing covered entities to bill States at AAC, despite subsequent HRSA guidance directing covered entities to refer to States' policies. Based on the 1993 HRSA guidance, these States reported that they expect covered entities to bill at AAC.

States do not have necessary pricing information to create prepay edits for 340B-purchased drugs; 20 States conduct postpay reviews to identify overpayments. States do not have access to AAC or 340B ceiling prices because of logistical and legal issues. States cannot create effective prepay edits because without AAC or 340B ceiling prices they are unable to tell when the amount that covered entities bill exceeds established State policies, which are typically AAC. Twenty States conduct postpay reviews to identify overpayments for 340B-purchased drugs.

Over half of States developed alternatives to the Medicaid Exclusion File to identify 340B claims and prevent duplicate discounts. Thirty States reported that they developed alternatives to the Medicaid Exclusion File to identify 340B claims and prevent duplicate discounts. Of these States, 26 contacted all or some of the covered entities in their States directly and created their own lists of covered entities that dispense

340B-purchased drugs to Medicaid patients. Nine of the thirty States instruct covered entities to identify specific 340B claims using the National Council for Prescription Drug Plan (NCPDP) Telecommunication Standard, an electronic standard used in pharmacies' prescription drug transactions, and two States instruct covered entities to bill using an alternative billing identification number. Ten of the thirty States that use alternatives reported that they do so because of inaccuracies in the Medicaid Exclusion File.

Fourteen States use only the Medicaid Exclusion File to identify 340B claims, and seven States reported that they do not use any method to identify 340B claims.

RECOMMENDATIONS

Based on our findings, we recommend that:

CMS direct States to create written 340B policies. CMS should direct States to create written 340B policies if they do not have them in place. CMS could also encourage States to consider the benefits and drawbacks of different 340B policies before setting their policies.

CMS inform States about tools they can use to identify claims for 340B-purchased drugs. CMS should inform States that they can have covered entities use the NCPDP Telecommunication Standard to identify 340B claims. CMS could also direct States to the Medicaid Exclusion File tutorial on HRSA's Web site.

HRSA share 340B ceiling prices with States. Providing 340B ceiling prices to States will help them create prepay edits to oversee their reimbursements for 340B-purchased drugs. Although the ACA gave HRSA authority to share 340B ceiling prices with covered entities, HRSA would have to seek legislative authority to share 340B ceiling prices with States.

HRSA, in conjunction with CMS, improve the accuracy of the Medicaid Exclusion File. HRSA should instruct covered entities to update their information in the Medicaid Exclusion File. HRSA could also work with States to ensure that covered entities' information in the file is correct. In addition, CMS could instruct States to notify HRSA if they find discrepancies between their records and the Medicaid Exclusion File.

AGENCIES' COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations. To address them, CMS plans to (1) inform States that they should incorporate 340B policies into their Medicaid State Plans, (2) inform States of alternative methods of identifying 340B claims that we identified in this report, and (3) facilitate communication between HRSA and States by providing a list of State Medicaid pharmacy directors to HRSA and instructing States to contact HRSA when errors in the Medicaid Exclusion File are found.

HRSA also concurred with our recommendations. However, it did not specify any actions it would take in response to them.

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INTRODUCTION

OBJECTIVE

To describe State Medicaid agencies' policies and oversight activities related to drugs purchased under the 340B Drug Discount Program (340B Program).

BACKGROUND

A 2005 Federal *qui tam* lawsuit alleged that some 340B-covered entities overcharged a State Medicaid agency for covered outpatient drugs. Partly in response to this lawsuit, Senator Charles Grassley requested that the Office of Inspector General (OIG) describe Medicaid reimbursement practices related to the 340B Program.

The 340B Program

The Veterans Health Care Act of 1992 established the 340B Program in section 340B of the Public Health Service Act (PHS Act).[1] The 340B Program requires drug manufacturers participating in Medicaid to provide discounted covered outpatient drugs to certain eligible health care entities, known as covered entities. Congress intended for the savings from discounted drugs purchased under the 340B Program "to enable [participating] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2]

Covered entities include disproportionate share hospitals, family planning clinics, and federally qualified health centers, among others.[3] As of October 2010, approximately 15,000 covered-entity locations were enrolled in the 340B Program.

To participate in the 340B Program, covered entities must register with the Health Resources and Services Administration (HRSA), the agency responsible for administering the 340B Program. After the entity has registered, HRSA enters the entity's information into HRSA's covered-entity database.[4] Provisions in the Patient Protection and

[1] Veterans Health Care Act of 1992, P.L. 102-585 § 602; PHS Act § 340B; 42 U.S.C. § 256b.

[2] H.R. Rep. No. 102-384, at 12 (1992)(Conf. Rep.).

[3] 42 U.S.C. § 256b(a)(4) enumerates the complete list of the types of entities eligible to become 340B-covered entities.

[4] The 340B Program registration form may be found on HRSA's Web site. Accessed at http://www.hrsa.gov on February 10, 2010.

Affordable Care Act (ACA) require HRSA to develop procedures for covered entities to annually update their information in the covered-entity database.[5]

Once approved, covered entities may purchase and dispense drugs under the 340B Program (hereinafter referred to as 340B-purchased drugs) through in-house pharmacies, or they may enter into contracts with retail pharmacies to dispense 340B-purchased drugs on their behalf.[6] A retail pharmacy dispensing 340B-purchased drugs on behalf of a covered entity is referred to as a contract pharmacy.

Covered entities may purchase drugs at or below 340B ceiling prices, which are the maximum prices drug manufacturers can charge for each 340B-purchased drug.[7] The 340B ceiling price is calculated using a statutorily defined formula based on the average manufacturer price (AMP) of drugs. In general, AMP is the average price paid to drug manufacturers for drugs distributed to retail community pharmacies.[8] Drug manufacturers must calculate and report AMP to the Centers for Medicare & Medicaid Services (CMS). The 340B ceiling price of a drug is generally much lower than its retail price.

Historically, neither CMS nor HRSA have shared AMP or the calculated 340B ceiling prices with State Medicaid agencies. The Deficit Reduction Act of 2005 gave CMS authority to share AMP with State Medicaid agencies. However, a Federal court injunction prohibited CMS from sharing AMP with State Medicaid agencies.[9, 10] The injunction was withdrawn in December 2010. HRSA has not shared 340B ceiling prices with State Medicaid agencies as it does not have legislative authority to do so. The ACA provided HRSA with the authority to share 340B ceiling prices with covered entities.[11]

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[5] ACA, P.L. 111-148 § 7102(a); PHS Act § 340B(d)(2)(B)(i); 42 U.S.C. § 256b(d)(2)(B)(i).

[6] 61 Fed. Reg. 43549, 43555 (Aug. 23, 1996).

[7] 42 U.S.C. § 256b(a)(1).

[8] 42 U.S.C § 1396r-8(k)(1). The statutory definition of AMP was redefined by the ACA to include direct manufacturer sales to retail community pharmacies as well as sales to wholesalers that supply retail community pharmacies, and to clarify which types of discounts should be excluded from the calculation. ACA, P.L. 111-148 § 2503(a)(2).

[9] 42 U.S.C. § 1396r-8(b)(3).

[10] National Association of Chain Drug Stores v. Leavitt, U.S. District Court for the District of Columbia, Dec. 19, 2007, Civil Action No. 1:07cv02017 (RCL).

[11] ACA, P.L. 111-148 § 7102(a), PHS Act § 340B(d)(1)(B)(iii), 42 U.S.C. §256b(d)(1)(B)(iii).

Medicaid Prescription Drug Benefit

All State Medicaid agencies offer outpatient prescription drug coverage and reimburse retail pharmacies for covered outpatient drugs dispensed to Medicaid patients. Overall, the Medicaid program spent approximately $23 billion on prescription drug coverage in 2009.[12] CMS monitors the Medicaid program at the Federal level.

State Medicaid agencies are expected to act as prudent buyers of drugs. State Medicaid agencies establish reimbursement methodologies for the ingredient cost of covered outpatient drugs. These reimbursement methodologies typically apply a discount to published prices, such as average wholesale price (AWP).[13, 14] These reimbursement methodologies are included in a State Medicaid agency's State plan and must be approved by CMS.[15]

State Medicaid agencies must also set a reasonable dispensing fee for all covered outpatient drugs they reimburse.[16] This fee reimburses a pharmacy's cost of providing the drug to a Medicaid patient.[17] Dispensing fees ranged from $1.50 to $12.50 per prescription in 2009.[18] Some State Medicaid agencies set higher dispensing fees for generic drugs to encourage generic prescribing.

State Medicaid agencies can use prepay edits and postpay reviews to prevent overpayments and ensure that reimbursements for covered outpatient drugs are consistent with established policies. Prepay edits enable processing systems to compare claim amounts to established reimbursement limits and automatically pay all or part of a claim, deny all or part of a claim, or suspend all or part of a claim for manual

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[12] 2009 Medicaid utilization data from CMS.

[13] Generally, the AWP is the price that a drug manufacturer sets for a drug and reports in publicly available sources.

[14] Studies and audits by OIG and other experts found that the AWP overstates the prices pharmacies pay by as much as 10 to 20 percent for brand-name prescription drugs. See OIG, Office of Audit Services, *Medicaid Pharmacy – Actual Acquisition Cost of Brand-Name Prescription Drug Products* (A-06-00-00023) and Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* (June 2005).

[15] 42 CFR § 447.518(a).

[16] 42 CFR § 447.512(b)(1).

[17] 42 CFR § 447.502.

[18] This range excludes dispensing fees for home intravenous therapy. *Medicaid Prescription Reimbursement Information by State – Quarter Ending September 2009*. Accessed at http://www.cms.hhs.gov on October 29, 2009.

review. Postpay reviews include formal audits and ongoing monitoring of billing patterns. Audits typically involve document reviews or site visits to identify overpayments and may result in monetary recovery.

340B Program and Medicaid

Covered entities choose whether to dispense 340B-purchased drugs to Medicaid patients, which affects how they interact with State Medicaid agencies.[19] If covered entities choose not to dispense 340B-purchased drugs to Medicaid patients, they instead dispense drugs that were purchased outside of the 340B Program. Because of that, covered entities can bill State Medicaid agencies at the standard reimbursement rates that those agencies have established for all retail pharmacies. Covered entities might make this choice because their State Medicaid agencies' standard reimbursement rates for covered outpatient drugs are higher than the purchase prices.[20] However, if covered entities elect to dispense 340B-purchased drugs to Medicaid patients, specific 340B policies and guidance apply. Approximately 42 percent of covered entities indicated that they had dispensed 340B-purchased drugs to Medicaid patients at the time of our study (first quarter of 2010).[21]

State Medicaid agencies' policies for 340B-purchased drugs. State Medicaid agencies may set specific policies for covered entities that dispense 340B-purchased drugs to Medicaid patients (340B policies), though CMS does not require them to do so. If a State Medicaid agency's 340B policy requires covered entities to bill and be reimbursed for 340B-purchased drugs at their actual acquisition costs (AAC), then the State Medicaid agency receives the full benefit of the 340B discount. If a State Medicaid agency's 340B policy allows covered entities to bill and be reimbursed for 340B-purchased drugs above AAC, then the State Medicaid agency shares a portion of the savings from the 340B discount with covered entities.

HRSA guidance to covered entities about billing State Medicaid agencies. HRSA has twice issued guidance for covered entities that bill State Medicaid

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[19] 65 Fed. Reg. 13983, 13984 (Mar. 15, 2000).

[20] The amount Medicaid reimburses, based on AWP, is typically higher than the 340B price, which is based on AMP. The difference in reimbursement for 340B- versus non-340B-purchased drugs is discussed in previous OIG reports. See OIG, *Cost Containment of Medicaid HIV/AIDS Drug Expenditures*, OEI-05-99-00611, July 2001; and OIG, *Medicaid's Mental Health Drug Expenditures*, OEI-05-02-00080, August 2003.

[21] According to the Medicaid Exclusion File, a subset of HRSA's covered entity database.

agencies for 340B-purchased drugs. In 1993, HRSA issued guidance stating:

> When a covered entity submits a bill to the State Medicaid agency for a drug purchased by or on behalf of a Medicaid beneficiary, the amount billed shall not exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer. … This will assure that the discount to the covered entity will be passed on to the State Medicaid agency.[22]

In 2000, HRSA altered its guidance, stating that it was reconsidering the AAC provision in its 1993 guidance, and directed covered entities to "refer to their respective Medicaid State agency drug reimbursement guidelines for applicable billing limits."[23] Provisions in the ACA require "the development of more detailed guidance describing methodologies and options available to covered entities for billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts."[24]

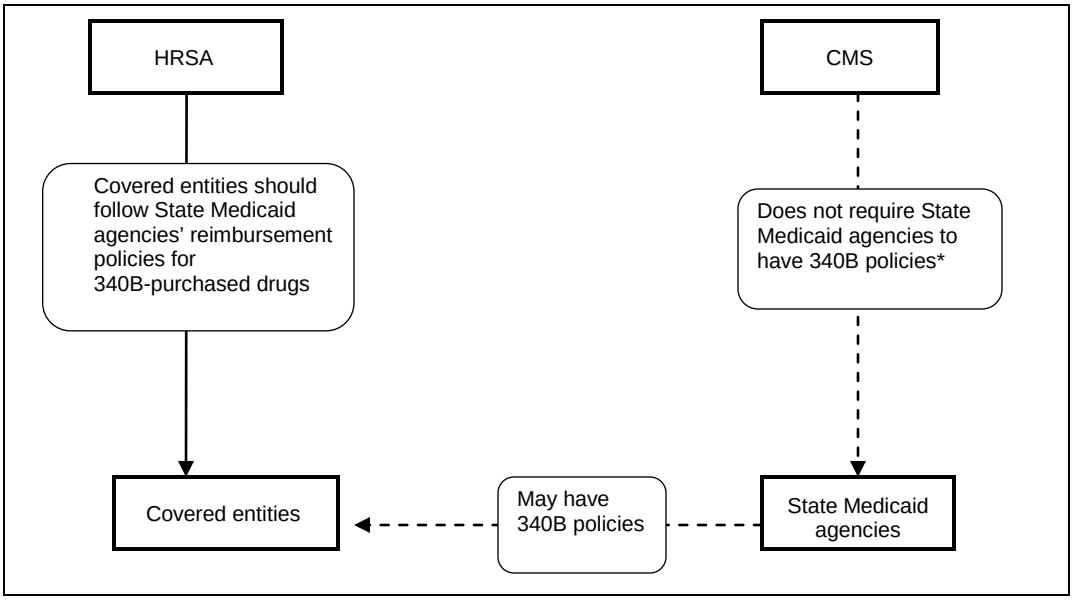
Chart 1 shows the policies and guidance related to covered entities dispensing 340B-purchased drugs to Medicaid patients.

[22] 58 Fed. Reg. 27293, 27293 (May 7, 1993).

[23] 65 Fed. Reg. 13983, 13984 (Mar. 15, 2000).

[24] ACA, P.L. 111-148 § 7102(a), PHS Act § 340B(d)(2)(B)(iii), 42 U.S.C. § 256b(d)(2)(B)(iii).

Chart 1: Policies and Guidance for Covered Entities That Dispense 340B-Purchased Drugs to Medicaid Patients



Source: OIG analysis of HRSA guidance and State Medicaid agencies' 340B policies, 2010.

***** CMS issued guidance to State Medicaid agencies in 1993 and 2000 advising them that covered entities are required to bill at AAC.

Preventing duplicate discounts. State Medicaid agencies obtain rebates from drug manufacturers for covered outpatient drugs dispensed to Medicaid patients.[25] To request Medicaid rebates, State Medicaid agencies send drug manufacturers quarterly invoices based on the type and quantity of drugs that the State reimbursed (utilization data).[26]

There is a potential for drug manufacturers to pay duplicate discounts if they pay Medicaid rebates to State Medicaid agencies for drugs that they have already sold to covered entities at discounted prices through the 340B Program. Duplicate discounts are prohibited by law.[27] To prevent duplicate discounts when claiming Medicaid rebates, State Medicaid agencies need to identify claims for 340B-purchased drugs (340B claims) and exclude them from the utilization data submitted to drug manufacturers.

[25] Drug manufacturers must enter into rebate agreements with the Secretary of the Department of Health & Human Services and pay quarterly rebates to State Medicaid agencies for their drugs to qualify for Medicaid reimbursement. Social Security Act, § 1927(a)(1).

[26] 42 U.S.C § 1396r-8(b)(2)(A).

[27] 42 U.S.C. § 256b(a)(5)(A).

HRSA established a Medicaid Exclusion File to help State Medicaid agencies identify 340B claims.[28] The file, a subset of HRSA's covered entity database, lists covered entities that dispense 340B-purchased drugs to Medicaid patients. State Medicaid agencies should be able to use this database to identify and exclude all of the 340B claims associated with these covered entities from the utilization data submitted to drug manufacturers.

Previous OIG Studies

OIG has conducted several studies on the 340B Program. Previous OIG studies found inaccuracies in covered entities' contact and participation information in HRSA's covered-entity database.[29] OIG also found that because of systemic problems with the accuracy and reliability of HRSA's record of 340B ceiling prices, HRSA was unable to appropriately oversee the 340B Program.[30] Finally, OIG found that covered entities were paying more than 340B ceiling prices, resulting in projected overpayments of $3.9 million in June 2005.[31]

METHODOLOGY

Scope

In response to the congressional request to look at reimbursement practices related to 340B-purchased drugs, this study describes State Medicaid agencies' policies for covered outpatient drugs purchased under the 340B Program. It also describes State Medicaid agencies' oversight of their reimbursements for 340B-purchased drugs, including State Medicaid agencies' ability to prevent overpayments for 340B-purchased drugs and duplicate discounts.

This study does not include information on covered entities' knowledge of States' policies or oversight. This study collected information from State Medicaid agencies, not from covered entities. Further, this study does not assess how different State Medicaid agencies' policies affect States' or

[28] 58 Fed. Reg. 27293, 27293 (May 7, 1993).

[29] OIG, *Deficiencies in the 340B Drug Pricing Program's Database*, OEI-05-02-00071, June 2004.

[30] OIG, *Deficiencies in Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, October 2005.

[31] OIG, *Review of 340B Prices*, OEI-05-02-00073, July 2006.

covered entities' finances. Finally, this study does not include information about State Medicaid agencies' policies for physician-administered drugs.[32]

Data Collection and Analysis

In March 2010, we surveyed 50 State Medicaid agencies and the District of Columbia's Medicaid agency (hereinafter referred to as States). We asked about State policies for 340B-purchased drugs, activities to monitor payments and enforce their policies, identification of 340B claims, and communication with CMS or HRSA regarding the 340B Program.

We conducted a pretest of the survey with two States and, where appropriate, revised the survey based on pretesters' feedback.

We emailed the survey to each State's Medicaid director with instructions to consult with or delegate the survey to a pharmacy director or other official familiar with the State's policies and oversight regarding 340B-purchased drugs. We received 51 replies for a 100-percent response rate. We followed up with States to clarify survey responses, where necessary.

For the purposes of this study, we counted a State as having a 340B policy only if it was documented in writing. We asked States to identify the types of documents that contained their policies and for citations when the policies were written in State laws, administrative codes, or pharmacy manuals. In some cases, we consulted the text of the written policies to clarify survey responses.

We exported survey results from Adobe LiveCycle to Microsoft Excel for analysis. We analyzed the survey data using Microsoft Excel. We also analyzed States' narrative responses for additional themes.

Limitations

This study relies on self-reported survey data from States. We did not verify States' responses.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

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[32] A physician-administered drug is a prescription drug that is directly administered to a patient by a physician during an outpatient office or hospital visit (e.g., certain injectible drugs). Because prescriptions for physician-administered drugs are not filled at retail pharmacies, they are generally not covered by the same reimbursement policies as other outpatient drugs.

Approximately half of States have written 340B policies that direct covered entities to bill Medicaid at cost for 340B-purchased drugs

Twenty-five States reported having 340B policies that direct covered entities to bill at cost (i.e., AAC) for 340B-purchased drugs. The policies appear in documents such as State laws, State administrative codes, State Medicaid pharmacy manuals, official letters to covered entities, and written agreements between States and covered entities.

Another State reported having a written 340B policy. However, its policy is to reimburse 340B-purchased drugs at AWP price minus a certain percentage. The percentages of AWP used in this calculation vary by each covered entity and range from 23 to 36 percent.[33]

See Appendix A for a list of States and whether they have written 340B policies.

Seven of the twenty-five States that have written 340B policies directing covered entities to bill at AAC provide a higher dispensing fee for 340B-purchased drugs than for non-340B-purchased drugs.[34] These States reported that they offer a higher dispensing fee for two main reasons. First, States reported offering a higher dispensing fee to extend additional resources to covered entities. Second, States reported that they set a higher dispensing fee for 340B-purchased drugs to motivate covered entities to dispense such drugs to Medicaid patients. Given that 340B ceiling prices are considerably lower than States' standard reimbursement rates for drugs, States might save money (even when paying a higher dispensing fee) if more covered entities dispensed 340B-purchased drugs to Medicaid patients.

Twenty-five States do not have written 340B policies

Of the 25 States that do not have written 340B policies, 16 reported that they want covered entities to bill at AAC for 340B-purchased drugs. Fifteen of these sixteen States reported that they do not have written 340B policies because they believe that HRSA's 1993 guidance to covered entities to bill at AAC is in effect. However, HRSA's 2000 guidance withdrew the AAC provision of the 1993 guidance and directed covered entities to follow State guidelines for billing 340B-purchased drugs.[35] States that rely on HRSA's old guidance and do not have

[33] The State's reimbursement for non-340B-purchased drugs is AWP minus 11.5 percent.

[34] Connecticut, Florida, Louisiana, Massachusetts, Oregon, Vermont, and West Virginia.

[35] 65 Fed. Reg. 13984 (Mar. 15, 2000).

written policies may not be able to enforce their expectation that covered entities bill at AAC.

Nine of the twenty-five States without written policies did not provide information about their expectations of covered entities' billing. However, according to four of these States, covered entities did not dispense 340B-purchased drugs to Medicaid patients at the time of our survey.

States with and without written 340B policies requested more Federal guidance

Eleven States reported that they want more Federal guidance on the intersection of Medicaid and the 340B Program.[36] Of these States, 5 have written policies and 6 do not.

About half of the 11 States reported that CMS and HRSA guidance to States and covered entities on this topic is inconsistent and insufficient given the 340B Program's complexity. For example, three States offered the following comments:

- It would be very helpful if more information and clarification on 340B rules and regulations by HRSA and CMS are shared with the States. Direct communication to States regarding how to track and monitor 340B covered entities would be appreciated.
- Intersections between 340B Program rules, pricing, AAC requirements, and Medicaid administration and payments are complex, inconsistent, and nonaligned.
- Neither [the 340B Program nor Medicaid] has enough guidance for the two to operate together.

These comments describe some of the complexity and potential for confusion that arises from the intersection of Medicaid and the 340B Program.

[36] Forty States did not comment on this issue in response to open-ended questions on our survey.

States do not have necessary pricing information to create prepay edits for 340B-purchased drugs; 20 States conduct postpay reviews to identify overpayments

States do not have 340B ceiling prices or covered entities' AAC for 340B-purchased drugs (together referred to as 340B drug prices).[37] States do not have 340B ceiling prices because they are calculated using AMP, to which States historically have not had access. Further, no States reported regularly collecting covered entities' AAC, even though 41 States expect covered entities to bill at AAC. The AAC varies by drug, quarter, and covered entity, so collecting it from covered entities regularly is difficult.

States cannot create effective 340B-specific prepay edits without 340B drug prices. In fact, 20 States reported that they need 340B drug prices to help them oversee their reimbursements for 340B-purchased drugs.[38] Without 340B drug prices, States are unable to tell when the amount billed exceeds established reimbursement policies, which typically are set at AAC. Without prepay edits, States reimburse 340B-purchased drugs at the amounts that covered entities bill—which may be above 340B prices—even if States have a policy of reimbursing covered entities at 340B prices. While one State reported using a 340B-specific edit, the edit relies on historic data to estimate one type of covered entities' acquisition costs for four drugs.

Although almost no States have 340B-specific prepay edits, 48 have general prepay edits. However, these edits are insufficient to prevent reimbursements above 340B prices. General prepay edits apply to all Medicaid outpatient prescription drug claims and prevent payment above a calculated maximum allowable amount. These edits are insufficient to prevent reimbursements above 340B prices for 340B claims because the maximum allowable cost typically is higher than the 340B price. This means that it is possible for a State to pay more than the 340B price even when capping reimbursement at the maximum allowable cost for each drug.

States that do not have written 340B policies may be particularly vulnerable to such overpayments. Without written policies to reference,

[37] The 340B ceiling prices and AAC may differ if a covered entity purchases a drug at a price lower than the 340B ceiling price.

[38] Thirty-one States did not comment on this issue in response to open-ended questions on our survey.

covered entities may not know how States expect them to bill. For example, a hospital industry group surveyed disproportionate share hospitals, a type of covered entity, in 27 States and found that many of the surveyed hospitals did not know what their States' 340B policies were.[39] If covered entities are not aware that a State expects them to bill at AAC for 340B-purchased drugs, they might bill above AAC and, in the absence of a 340B-specific prepay edit, a State would reimburse those covered entities above AAC.

Twenty States conduct postpay reviews to identify overpayments for 340B-purchased drugs

Twenty States reported that they conduct postpay reviews of reimbursements for 340B-purchased drugs. Fourteen States reported that they conduct audits, and eight reported that they conduct ongoing monitoring (two States do both). Of the 20 States that conduct postpay reviews, 14 have written 340B policies.

Of the 14 States that conducted audits, 8 reported finding overpayments for 340B-purchased drugs. These 8 States audited 41 covered entities over a 10-year period and found approximately $2.6 million in overpayments. The 41 audited covered entities represent approximately 3 percent of the covered entities in the 8 States. Generally, these States reviewed invoices to compare covered entities' AAC to the States' reimbursements. States conducted these audits between October 1999 and June 2009.

Most of the submitted audit documentation did not describe why overpayments occurred, although one State that audited hospital outpatient pharmacies found that the hospitals overbilled the State because of errors in hospital billing systems. The hospitals reported to the State that their billing systems had not been updated in time to reflect quarterly changes to 340B drug prices.

Eight States reported that they monitor reimbursements after claims for 340B-purchased drugs are paid by conducting periodic checks of covered entities' billing. In some cases, States compare their estimates of AAC to covered entities' billed amounts to identify potential overpayments. For example, one State compares reimbursements for 340B-purchased drugs to 73 percent of the amount it reimburses for drugs purchased outside the 340B Program. Estimating AAC could lead to imprecise identification of

[39] Safety Net Hospitals for Pharmaceutical Access, *Shedding Light on Medicaid Billing Requirements: A Survey of State Policies Addressing the Drug Billing Practices of 340B Hospitals*, November 16, 2009. Accessed at http://www.snhpa.org/ on November 20, 2009.

overpayments because 340B drug prices fluctuate each quarter and do not necessarily fluctuate in concert with other drug prices.

Over half of States developed alternatives to the Medicaid Exclusion File to identify 340B claims and prevent duplicate discounts

Thirty States reported that they use alternatives to the Medicaid Exclusion File, a subset of HRSA's covered-entity database, to identify 340B claims. Ten of the thirty States reported that they developed alternatives because the file contains inaccurate data. Previous OIG work found inaccuracies in other fields of HRSA's covered-entity database, such as enrollment status, and billing and shipping information.[40]

States need accurate data to identify 340B claims so they do not subject drug manufacturers to duplicate discounts by including 340B claims in utilization data submitted for Medicaid rebates. Alternatively, States may forgo rebates they are owed if non-340B claims are incorrectly excluded from utilization data submitted for Medicaid rebates.

Of the 30 States that created alternatives to the Medicaid Exclusion File, 26 contacted all or some covered entities directly and created their own lists of covered entities that dispense 340B-purchased drugs to Medicaid patients.

On the other hand, 11 of the 30 States instructed covered entities to identify 340B claims. These States instruct covered entities to identify 340B claims in one of two ways. Nine States instruct covered entities to identify 340B claims using the National Council for Prescription Drug Plan (NCPDP) Telecommunication Standard 5.1 when they submit a 340B claim.[41] Two States instruct covered entities to bill 340B claims using an alternative billing identification number provided to covered entities that bill Medicaid for 340B-purchased drugs.

Seven States use their own lists and instructions to covered entities to identify 340B claims.

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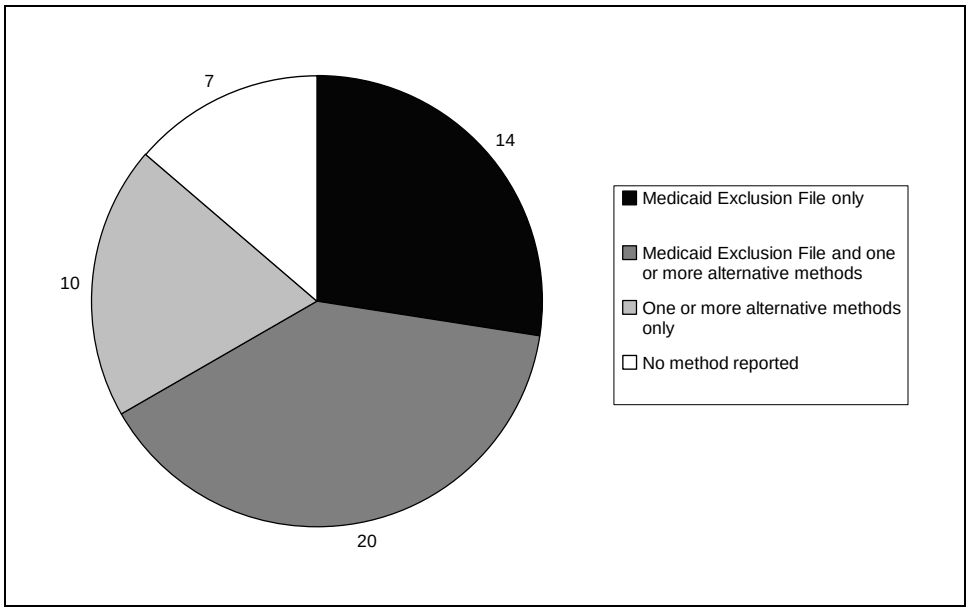
[40] Previous OIG work found inaccuracies in HRSA's covered-entity database related to covered entities' enrollment status and address, as well as billing and shipping information. *Deficiencies in the 340B Drug Discount Program's Database* (OEI-05-02-00071). Accessed at http://oig.hhs.gov/ on May 13, 2010.

[41] The NCPDP Telecommunication Standard 5.1 is the electronic transaction standard that pharmacies and payers use to submit and exchange information about prescription drug claims. The new version of the NCPDP Telecommunication Standard (version D.0) reserves a specific value, 08, to indicate a 340B claim.

Chart 2 shows States' reported alternative methods to identify 340B claims.

Chart 2: States' Methods To Identify 340B Claims



Source: OIG analysis of survey data, 2010.

Neither of the alternative methods employed by the 30 States necessarily ensures accurate identification of 340B claims. States' lists of covered entities that dispense 340B-purchased drugs to Medicaid patients may not be more accurate than the Medicaid Exclusion File. Additionally, States that instruct covered entities to identify 340B claims must rely on covered entities to do so accurately and consistently.

Fourteen States rely solely on the Medicaid Exclusion File to identify 340B claims, and seven States do not use any method to identify 340B claims

Fourteen States reported that they use only the Medicaid Exclusion File to identify 340B claims. As discussed previously, 10 States reported inaccuracies in the file and use alternative methods to identify 340B claims. Inaccuracies in the file could mean that these 14 States may not accurately identify 340B claims. When States do not accurately identify 340B claims, they may subject drug manufacturers to duplicate discounts or not claim Medicaid rebates that they are owed.

Seven States did not report a method of identifying 340B claims and may, as a result, submit utilization data to drug manufacturers that include 340B claims, subjecting manufacturers to duplicate discounts. Of these seven States, four reported that, at the time of the survey, no covered entities had submitted 340B claims. One State reported that it was

implementing a system of identifying 340B claims. Two States did not report a reason for not identifying 340B claims.

RECOMMENDATIONS

Our findings raise concerns about States' ability to conduct oversight activities related to 340B-purchased drugs. Nearly half of States (25 of 51) do not have 340B policies. Fifteen of these States reported that they expect covered entities to bill 340B-purchased drugs at AAC based on the rescinded 1993 HRSA guidance. Additionally, States do not have drug pricing information necessary to create prepay edits for 340B-purchased drugs to prevent overpayments. Finally, over half of States developed alternatives to the Medicaid Exclusion File to identify 340B claims and prevent duplicate discounts. Some of these States reported that they had to develop alternatives because of inaccurate data in the Medicaid Exclusion File.

Based on these findings, we recommend that:

CMS direct States to create written 340B policies

CMS should direct States to create written 340B policies if they do not have them because current HRSA guidance directs covered entities to follow States' 340B policies. CMS should encourage States to make their written policies widely available to interested parties, including covered entities. CMS should also alert States to any new HRSA-issued guidance about covered entities billing States for 340B-purchased drugs.

CMS could also encourage States to consider the benefits and drawbacks of different 340B policies before setting their policies (e.g., consider how State expenditures might be affected if covered entities decide to dispense non-340B purchased drugs to Medicaid patients). As part of this effort, States could work with covered entities to explore policy options that might result in savings for the States and the covered entities. HRSA's Web site has information about covered entities and the 340B Program that States could consult in setting their policies.

CMS inform States about tools they can use to identify claims for 340B-purchased drugs

CMS should inform States of the multiple ways to identify 340B claims. States can instruct covered entities to use the NCPDP Telecommunication Standard to identify claims for 340B-purchased drugs. The new version of the NCPDP Telecommunication Standard (version D.0) reserves a specific value, 08, to indicate that a claim is for a 340B-purchased drug.

CMS could also direct States to the Medicaid Exclusion File tutorial on HRSA's Web site. HRSA developed the tutorial to help States and others understand how to use the file to identify covered entities dispensing 340B-purchased drugs to Medicaid patients.

HRSA share 340B ceiling prices with States

Providing 340B ceiling prices to States would help States create prepay edits to ensure that they accurately reimburse 340B-purchased drugs. Although the ACA gave HRSA authority to share 340B ceiling prices with covered entities, HRSA would have to seek legislative authority to share those prices with States. Once given that authority, HRSA could use the mechanism that it establishes to share 340B ceiling prices with covered entities to share those prices with States as well.

HRSA, in conjunction with CMS, improve the accuracy of the Medicaid Exclusion File

HRSA should instruct covered entities to update their information in the Medicaid Exclusion File as part of the new annual database recertification required by the ACA.

HRSA could also work with States to ensure that covered entities' information in the Medicaid Exclusion File is correct. HRSA could obtain updated information on covered entities from States that have verified all or part of the file for their State. To assist HRSA, CMS could provide HRSA with contacts familiar with the covered entities in their respective States. CMS could also instruct States to notify HRSA if they find discrepancies between their records and the Medicaid Exclusion File.

AGENCIES' COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations. To address them, CMS plans to (1) inform States that they should incorporate 340B policies into their Medicaid State Plans, (2) inform States of alternative methods of identifying 340B claims that we identified in this report, and (3) facilitate communication between HRSA and States by providing a list of State Medicaid pharmacy directors to HRSA and instructing States to contact HRSA when errors in the Medicaid Exclusion File are found.

CMS requested further information regarding our statement in the first recommendation about States conducting cost-benefit analyses before

setting their policies. In response, we revised the language in the recommendation.

HRSA generally concurred with our recommendation that it share 340B ceiling prices with States. HRSA agreed that such sharing may improve Medicaid reimbursement if States use the information to design 340B policies that result in savings for States and covered entities. HRSA also emphasized that 340B policies should take into account the impact on covered entities and additional costs associated with the patient populations they serve. HRSA did not, however, specify any action it would take to address this recommendation. We continue to recommend that HRSA take steps to share 340B ceiling prices with States.

HRSA also concurred with our recommendation to improve the accuracy of the Medicaid Exclusion File. HRSA stated that its guidance from March 2000 requires covered entities to keep their information in the file up to date. HRSA also encouraged States to share any discrepancies found between States' records and the file, noting that such information sharing would improve oversight of the 340B Program and compliance with the prohibition of duplicate discounts. However, HRSA did not indicate that it would take new action to instruct covered entities to update their information in the Medicaid Exclusion File. We continue to recommend that HRSA include specific instruction to covered entities to update their information in the file as part of any new guidance it issues defining the new annual database recertification required by the ACA.

HRSA provided technical comments on the report, which we incorporated where appropriate.

For the full text of CMS and HRSA comments, see Appendix B.

APPENDIX ~ A

Table A-1: State Medicaid Agencies' 340B Policies

State	Written Policy	Location(s) of Written Policy
Alabama	✔	State administrative code
Alaska	✔	State administrative code, pharmacy manual, official letter
Arizona	-	-
Arkansas	✔	Official letter
California	✔	State law, pharmacy manual
Colorado	-	-
Connecticut	✔	State law
Delaware	-	-
District of Columbia	-	-
Florida	✔	State law, state administrative code, pharmacy manual, official letter
Georgia	✔	Pharmacy manual
Hawaii	✔	State law, state administrative code
Idaho	-	-
Illinois	✔	Pharmacy manual, written agreements
Indiana	-	-
Iowa	✔	Pharmacy manual, official letter
Kansas	-	-
Kentucky	✔	State administrative code, pharmacy manual
Louisiana	✔	State administrative code, pharmacy manual
Maine	-	-
Maryland	-	-
Massachusetts	✔	State administrative code
Michigan	✔	Pharmacy manual
Minnesota	✔	Written agreements
Mississippi	-	-
Missouri	-	-
Montana	✔	Official letter

continued on next page

Table A-1: State Medicaid agencies' 340B Policies, Continued

State	Written Policy	Location(s) of Written Policy
Nebraska	-	-
Nevada	-	-
New Hampshire	-	-
New Jersey	-	-
New Mexico	-	-
New York	✔	State law
North Carolina	✔	Pharmacy manual
North Dakota	-	-
Ohio	-	-
Oklahoma	✔	Official letter
Oregon	✔	Pharmacy manual
Pennsylvania	-	-
Rhode Island	-	-
South Carolina	-	-
South Dakota	✔	State administrative code
Tennessee	✔	Written agreements
Texas	✔	State administrative code, pharmacy manual, written agreements
Utah	-	-
Vermont	✔	Written agreements
Virginia	-	-
Washington	✔	State administrative code, pharmacy manual
West Virginia	✔	Pharmacy manual, written agreements
Wisconsin	-	-
Wyoming	-	-

Source: Office of Inspector General analysis of survey data, 2010.

APPENDIX ~ B

Agency Comments

CMS Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAR 2 3 2011

TO: Daniel R. Levinson
Inspector General

FROM: Donald M. Berwick, M.D. /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: State Medicaid Policies and Oversight Activities Related to 340B Purchased Drugs (OEI-05-09-00321)

Thank you for the opportunity to review and comment on the OIG Draft Report entitled, "State Medicaid Policies and Oversight Activities Related to 340B Purchased Drugs," (OEI-05-09-00321). The purpose of this report was to described State Medicaid agencies' policies and oversight activities related to drugs purchased under the 340B Drug Discount Program.

The 340B Drug Discount Program requires drug manufacturers to provide covered outpatient drugs to certain eligible entities at or below a statutorily defined ceiling price. The 340B Program is administered through the Health Resources and Services Administration (HRSA). State Medicaid agencies may set specific policies for covered entities that dispense 340B drugs to Medicaid patients.

The OIG found that approximately half of States have written 340B policies that direct covered entities to bill Medicaid at cost for 340B-purchased drugs. Over half of States without written policies reported that they rely on HRSA's 1993 guidance directing covered entities to bill States at actual acquisition cost (AAC) and expect covered entities to bill at AAC. The OIG also found that States do not have adequate information to create prepay edits for 340B-purchased drugs due to logistical and legal issues. However, twenty States conduct postpay reviews to identify overpayments for 340B-purchased drugs. Finally, the OIG found that States employ a variety of methods to identify 340B claims to prevent duplicate discounts. These methods include contacting covered entities directly and maintaining their own list, utilizing HRSA's Medicaid Exclusion File, instructing covered entities to use the National Council for Prescription Drug Plans (NCPDP) Telecommunications Standard, and instructing covered entities to bill Medicaid using an alternative billing identification number.

OIG Recommendation

CMS should direct States to establish written 340B policies if they do not already have policies in place. Further, CMS should alert States to any new guidance HRSA issues about covered

entities billing States for 340B-purchased drugs. CMS could also encourage States to conduct cost-benefit analyses of different 340B policies before setting their policies.

CMS Response

CMS concurs with the recommendation regarding States establishing written 340B policies. We recognize the importance of this issue to covered entities and will inform Medicaid State agencies that they should incorporate how they reimburse 340B covered entities in their Medicaid State Plan. CMS also concurs with the recommendation to alert States when HRSA issues guidance relevant to the Medicaid program. We have historically provided States with guidance in such instances and will continue this practice in the future.

CMS requests further information regarding the recommendation to encourage States to do a cost benefit analysis of different 340B policies as the OIG also did not provide any further specificity as to the need for such an analysis, what it would be based on, and how States should compare options for maximum benefit.

OIG Recommendation

CMS should inform States of the tools they can use to identify 340B claims, such as instructing that covered entities use the NCPDP Telecommunication Standard to identify 340B claims. States can also use the Medicaid Exclusion File tutorial on HRSA's Web site.

CMS Response

CMS concurs and will initiate the development of a release to States after this report is released in final.

OIG Recommendation

CMS can assist HRSA by providing HRSA with the appropriate State contacts that are familiar with the covered entities in their respective States. In addition, CMS could instruct States to notify HRSA if they find discrepancies between their records and the Medicaid Exclusion File.

CMS Response

We concur. CMS will make the list of State Medicaid pharmacy directors available to HRSA Office of Drug Pricing staff. We will also obtain a contact at HRSA's ODP and instruct States to contact them when errors in the Medicaid Exclusion File are found. We will also include this latter information in the release to States after this report is released in final.

CMS would, again, like to thank the OIG for their efforts in identifying and describing State Medicaid agencies policies and oversight activities in regards to the 340B Drug Discount Program.

HRSA Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville MD 20857

MAR 16 2011

TO: Inspector General

FROM: Administrator

SUBJECT: Office of Inspector General Draft Report: "State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs" (OEI-05-09-00321)

This is in response to the Office of Inspector General's (OIG) request for comments on the draft report: "State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs" (OEI-05-09-00321). Attached are the Health Resources and Services Administration's comments on this draft report. Under separate cover, technical comments are also being sent to OIG. If you have any questions, please contact Sherry Angwafo in HRSA's Office of Federal Assistance Management at (301) 443-9547.

/S/

Mary K. Wakefield, Ph.D., R.N.

Attachment

Health Resources and Services Administration's Comments on the Office of Inspector General Draft Report "State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs" (OEI-05-09-00321)

The Health Resources and Services Administration (HRSA) is pleased with the opportunity to comment on the above referenced draft report. HRSA believes that the report provides needed additional information about State Medicaid Agencies' policies and oversight activities related to drugs purchased under the 340B Drug Pricing Program. HRSA believes that this report will both assist State Medicaid Agencies in developing improved policies and assist HRSA in providing oversight to the 340B Drug Pricing Program.

OIG Recommendation:

HRSA share 340B ceiling prices with States
Providing 340B ceiling prices to States will help States create prepay edits to ensure that they accurately reimburse 340B-purchased drugs. Although the ACA gave HRSA authority to share 340B ceiling prices with covered entities, HRSA would have to seek legislative authority to share 340B ceiling prices with States. Once given authority, HRSA could use the same mechanism that it establishes to share 340B ceiling prices with covered entities to also share those prices with States.

HRSA Response:
HRSA generally concurs with this recommendation that encourages additional data sharing between HRSA and the states. HRSA agrees that sharing the 340B ceiling price calculation with the states may improve Medicaid reimbursement if utilized in a manner consistent with other OIG recommendations that reimbursement policy options be designed to result "in savings for both states and covered entities." Such reimbursement policies should take into account the impact on safety-net providers participating in the 340B Program and any additional reasonable costs associated with the patient populations served and costs of compliance with all 340B requirements.

OIG Recommendation:

HRSA, in conjunction with CMS, improve the accuracy of the Medicaid Exclusion File.
HRSA should instruct covered entities to update their information in the Medicaid Exclusion File as part of the new annual database recertification required by the ACA.

Additionally, HRSA could work with States to ensure that covered entities' information in the Medicaid Exclusion File is correct. HRSA could obtain updated information on covered entities from States that have verified all or part of the Medicaid Exclusion File for their State. To assist

HRSA, CMS could provide HRSA with appropriate State contacts that are familiar with the covered entities in their respective States. In addition, CMS could instruct States to notify HRSA if they find discrepancies between their records and the Medicaid Exclusion File.

HRSA Response:
HRSA concurs with the recommendation. HRSA emphasizes that covered entities are already required to keep their information in the Medicaid Exclusion file accurate and up to date in accordance with Federal Register Notice 65 Fed. Reg. 13983 (Mar. 15, 2000).

HRSA also encourages states to provide information regarding any discrepancies between their records and the Medicaid Exclusion File. The increased sharing of information between states and HRSA will result in improved oversight, integrity, and administration of the 340B Drug Pricing Program and prohibit the payment of Medicaid rebates by manufacturers on 340B–purchased drugs which violate the guidelines of the program.

ACKNOWLEDGMENTS

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Thomas F. Komaniecki, Deputy Regional Inspector General.

Kelly Waldhoff served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Chicago regional office who contributed to the report include Adam Freeman, Abby Lopez, and Carolyn Pichert; other central office staff who contributed include Heather Barton.

Office of Inspector General

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